Minutes of Meeting

Tertiary Care Advisory Committee

Date: 17 July 2007 Time: 1:00 PM

Location: Conference Room 401

ATTENDANCE:

Council: Present: Gregory Allen, DO, John Flynn, Catherine Graziano, RN. PhD, Sam Havens, Robert S.L. Kinder, Joan Kwiatkowski, Gus Manocchia, MD, Robert J. Quigley, D C (Chair), and Ed Quinlan

Not Present: Mark Reynolds

Staff: Valentina D. Adamova, Jay Beuchner, Michael Dexter, Joseph G. Miller, Linda M. Tetu-Mouradjian RN, Donald C. Williams

Public: (see attendance attached)

1. Call to Order and Approval of Minutes

The meeting was called to order at 1:00 PM. The chairman noted that the conflict of interest forms were available to any member who may have a conflict. Copies of the 15 May 2007 meeting minutes were

distributed to the members. A motion was made, seconded and passed by a vote of nine in favor and none opposed to approve and accept the minutes.

The Chairman requested a motion for the extension of time for the availability of minutes pursuant to the Open Meetings Act. A motion was made, seconded and passed by a vote of nine in favor and none opposed that the availability of the minutes for this meeting be extended beyond the time frame provided for under the Open Meetings Act. Those members voting in favor of the motion were: Allen, Flynn, Graziano, Havens, Kinder, Kwiatkowski, Manocchia, Quigley and Quinlan.

2. General Order of Business

The Chairman reported that the recommendations from the TCAC on minimum volumes for Esophageal and Pancreatic cancer surgery were sent to the director. In addition he asked staff to describe the next steps in the process once recommendations have been established and accepted by the Director. M. Dexter reported to the committee that the Director has indicated that the Department would be moving ahead and developing rules and regulations based on the TCAC's recommendations. He noted that there were two outstanding issues that needed to be resolved in the process of promulgating the regulations. The first was acceptable mortality rates for facilities that do meet the minimum volumes. The second issue included making

decisions on the ramp up period that hospitals would be permitted to prepare to achieve minimum volume standards.

M. Dexter discussed the time line for the regulatory process and projected that regulations may be in place by January 2008 and made a couple of suggestions regarding methods and timelines for the hospitals to prepare to meet the regulations. The first was to permit the hospitals a two-year ramp up period and enforce the regulations at that point or permit each individual facility to develop a plan to address this issue. Additionally, he pointed out that some facilities have been doing these procedures on and off over the years. He explained that once the rules and regulations were promulgated they would be subjected to public hearing which may give rise to new ideas and other issues for the committee's consideration.

The Chairman asked the committee members if they had any questions regarding the process of promulgating rules and regulations. A member asked M. Dexter to define the term ramp up as it related to the regulations. M. Dexter replied that the term ramp up needed to be defined in the regulations. Currently the TCAC recommendation is that there be a provision that includes a 2-year ramp up period.

E. Quinlan asked if the term ramp up referred to quantity, or mortality, or back-up resources. M. Dexter stated that ramp means hospitals' would be given a 2 year period to meet minimum volume standards

for the aforementioned procedures which would involve creating and /or maintaining the necessary infrastructure (equipment, staffing or other types of resources) the facility would need to perform these procedures. A member asked if the regulations were approved by the Department would individual hospitals need to draft a plan to address the ramp up period and would the plan need Department approval? Mr. Dexter stated it was too soon to answer that question because the Department was at the beginning of the process.

The Chairman stated that any recommendations made the TCAC regarding procedures could be reviewed and revised at a later date. In addition, he asked if there were any questions or comments from the public representatives present.

The Chairman stated that the main item to be addressed by the members was angioplasty. He then introduced H. Zimmerman to present a review of the current literature entitled Developments in Angioplasty and the Epidemiology of Coronary Artery Disease in Rhode Island. Topics discussed included: Current Regulations, Improvements in Coronary Angioplasty, Recent Volume-Outcome Studies (Mc Grath et al. 2000, Kimmel et al. 2002, Epstein et al. 2004, Hannan et al. 2005, and Moscucci et al. 2005), New Guidelines, An Update on Clinical Competence on Cardiac Interventional Procedures, Trends in Hospitalizations for Coronary Atherosclerosis and Acute Myocardial Infarction, US 1996-2005, trends in utilization of coronary revascularization, US 2002-2005, rates of death and heart

failure in Acute Coronary Syndrome, 1999-2006 and Percent Change in Angiography and Angioplasty use in RI 2004-2006.

The Chairman asked the members if they had questions of H. Zimmerman. S. Havens asked if there was any information available on the operators performing these procedures. Mr. Zimmerman stated that the hospitals collect this type of data and voluntarily report it to the Department of Health upon request. Another member asked H. Zimmerman about mortality rates related to the aforementioned procedures. Mr. Zimmerman replied that the Department has mortality rates for each individual hospital but not by operators. Additionally, he responded that the problem with small volume is statistical reliability.

M. Dexter asked about whether there was a change in the ACC/AHA guidelines relating to primary angioplasty. Mr. Zimmerman replied that the recommendations have not changed.

E. Quinlan asked how many states have established volume standards. H. Zimmerman replied 50% according to national survey data (2005) and the thresholds were 75 per operator per institution. S. Havens inquired about the current relationship with standards and what is happening at Landmark Medical Center. M. Dexter replied that the required volume for Landmark Medical Center was 400 angioplasties and 500 cardiac surgeries per year. In addition, Landmark Medical Center has a three-year ramp up period for cardiac

surgery which should end April 2008.

Dr. Cody, Chairman of Surgery, from Landmark Medical Center complimented Mr. Zimmerman on his presentation. Additionally, he commented in regards to surgical outcomes and recommended that the TCAC focus on patient outcomes in both high and low volume facilities. He also suggested that the TCAC direct their attention to operators performing the aforementioned procedures. He stated that it is important to look at particular operators because at least in the case of Landmark, a number of operators perform surgery at Landmark, Miriam, and RIH. He pointed out that it is less cut and dry than just looking at numbers of procedures in institutions due to operators working at a number of hospitals.

Dr. Cody stated that interpreting outcomes is a little more complex due to a number of variables to be considered which include: institutional factors, availability of ancillary services, and case selection per individual surgeon. In addition, many of these operators are actually performing higher volumes than predicted because they are operating at multiple hospitals. He suggested that when setting guidelines for hospitals it is important to know all the data. He also pointed out that it is nice to have the numbers of procedures but what are the results, what are the mortality rates, and how are we doing? He stated he thought asking these types of questions would put everything in perspective and that focusing on operators would actually provide a broader picture. He pointed out that most of the

studies presented pertained to operators that were faculty members at one large institution unlike Rhode Island.

S. Havens asked H. Zimmerman about the interpretation of statistical validity when dealing with low numbers (300-400) procedures performed in hospitals. Mr. Zimmerman replied that low numbers of procedures need to be reviewed over a period of years that one year is not a good measure. The Chairman asked if the hospitals could provide data on operators. J. Buechner stated that operator information is provided every year according to regulations, and these data include the number of procedures, the outcomes, and the number of procedures by operator.

M. Dexter asked Mr. Zimmerman when he would be able to provide a report on the current state of advice from the ACC and AHA on primary angioplasty with and without on site cardiac surgery. Mr. Zimmerman stated with his current schedule two months.

The Chairman suggested that the committee may want to hear presentations from local physicians that are performing these procedures. Additionally he suggested the committee meet on a monthly basis. The members agreed that presentations from local physicians should be the next step. E. Quinlan recommended that the members visit a facility to gain more insight and the members agreed.

3. Adjournment

The next meeting of the TCAC will be held on August 21, 2007 at 1:00 PM in Room 401. There being no further business the meeting was adjourned at 2:15 PM.

Respectfully submitted,

Linda M. Tetu-Mouradjian RN